

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: G. Cevc, et al.
Application No: 10/037,480
Filed: January 4, 2002
For: **Method for the Improvement of Transport Across Adaptable Semi-Permeable Barriers**
Examiner: Fortuna, Ana M.
Art Unit: 1797

Mail Stop: Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Statement of Substance of Interview

SIR:

The undersigned appreciates the courtesies extended by Examiner Fortuna in the telephonic interview of August 14, 2008.¹

In the Interview, the Examiner requested authorization to enter an Examiner's Amendment to amend claims 40 and 122 and to cancel claim 125. The undersigned authorized the Examiner's Amendment.

The Examiner also requested that the undersigned provide her with a "Brief Description of the Drawings" section to add to the specification in the Examiner's Amendment. The undersigned submitted to Examiner Fortuna via e-mail a "Brief Description of the Drawings" section on August 15, 2008. A copy of the "Brief Description of the Drawings" section and the August 15, 2008 e-mail is attached hereto as "Attachment A" for the Office's convenience.

¹ The undersigned notes that the Examiner-Initiated Interview Summary form mailed on August 21, 2008 erroneously indicates that the Interview took place on October 14, 2008, rather than August 14, 2008.

The "Brief Description of the Drawings" section submitted on August 15, 2008 was added to the specification via an Examiner's Amendment as part of an Examiner-Initiated Interview Summary mailed on August 21, 2008. A copy of the Examiner's Amendment is attached hereto as "Attachment B" for the Office's convenience.

It has recently come to the attention of the undersigned that a "Brief Description of the Drawings" section was previously submitted to the Office via an Amendment and Reply under 37 C.F.R. § 1.111 filed October 5, 2007. A copy of the October 5, 2007 Amendment is attached hereto as "Attachment C" for the Office's convenience. The undersigned believes that the "Brief Description of the Drawings" section submitted on August 15, 2008 does not materially differ from the "Brief Description of the Drawings" section of the Amendment filed on October 5, 2007.

Should the Examiner have any questions in connection with the above, she should feel free to contact the undersigned at 212-497-7731 to discuss the same.

Respectfully submitted,

Dated: October 7, 2008

By: /Gina R. Gencarelli/
Gina R. Gencarelli
Reg. No. 59,729

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ATTACHMENT A

Gencarelli, Gina

From: Gencarelli, Gina
Sent: Friday, August 15, 2008 10:42 AM
To: 'ana.fortuna@uspto.gov'
Cc: Langer, Matthew E.
Subject: U.S. Application Serial No. 10/037,480 (atty docket no. 35946-703.301)
Attachments: 35946-703.301 Brief Description of the Drawings_(PALJB1_3428843_1).DOC

Dear Examiner Fortuna,

As we discussed yesterday, attached is a "brief description of the figures" section to be added to the specification of the above-referenced application at page 54, before line 1.



35946-703.301
Brief Descriptio...

Please let me know if you need anything else.

Best regards,
Gina

Gina R. Gencarelli
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U.S. Application Serial No. 10/037,480

Brief Description of the Drawings (to be added to the specification at page 54, before line 1 at the request of Examiner Fortuna)

August 15, 2008

Brief Description of the Drawings

Figure 1 shows the recovery of relative activity (penetrant amount) in different layers of the skin as a function of applied activity (dose).

Figure 2 shows the amount of carrier derived radioactivity (^3H -DPPC) in the blood as a function of time and epicutaneously administered penetrant quantity, expressed as percentage of applied dosage.

Figure 3 indicates the relative accumulation of carrier derived radioactivity in various organs at two different time points after an increasing mass of ultradeformable carriers has been administered on the skin.

Figure 4 shows the absolute penetrant distribution profile (in arbitrary units) in different layers of the skin as a function of applied activity (dose).

Figure 5 shows the total amount of penetrant recovered in different tissues (skin, blood, liver) at different times after the administration of an increasing quantity of ultradeformable penetrants on the skin grows with the applied dose per area.

Figure 6 shows the time dependence of penetrant derived radioactivity in the blood as a function of epicutaneously administered suspension volume (lipid amount).

Figure 7 shows the penetrant derived radioactivity in the blood as a function of epicutaneously administered dose measured 8 h or 24 h after the application.

Figure 8 shows the results obtained by measurement of the mean vapor transmission rate

(MVTR) of five microporous polyethylene membranes, four polyurethane membranes and one polycarbonate track etched membrane.

Figure 9 is a diagram showing the principle of the “switching-effect,” which e.g. is observed in connection with the inventive hydrophobic mesh-membranes.

Figure 10 shows the penetrability of three different microporous polyethylene membranes for Transfersomes namely Type-C; Solupor-E011 D, Solupor-8P07A and Solupor-10P05A (DSM Solutech, Heerlen, The Netherlands).

Figure 11 shows a schematic diagram of a multicompartment patch having external compartments according to the present invention in form of twin syringe serving as storage compartments with mixing tubing or T-piece connector attached to the patch.

Figure 12 shows a schematic diagram of a multicompartment patch according to the present invention having vertically stacked compartments.

Figure 13 shows a schematic diagram of a multicompartment patch according to the present invention with a side-by-side alignment of compartments with vertically introduced septum.

Figure 14 shows a schematic diagram of a multicompartment patch according to the present invention having a side-by-side alignment of compartments with separating lamination.

ATTACHMENT B

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gina R. Genkarely on 10/14/08.

The application has been amended as follows:

Cancel claim 125.

In claim 40, line 2, delete "smaller than 100", and insert - -20-100- -.

In claim 122, line 3, delete "smaller than 100", and insert - -20-100- -.

In the specification, page 54, line 1 insert

-Brief Description of the Drawings

Figure 1 shows the recovery of relative activity (penetrant amount) in different layers of the skin as a function of applied activity (dose).

Figure 2 shows the amount of carrier derived radioactivity (^3H -DPPC) in the blood as a function of time and epicutaneously administered penetrant quantity, expressed as percentage of applied dosage.

Figure 3 indicates the relative accumulation of carrier derived radioactivity in various organs at two different time points after an increasing mass of ultra-deformable carriers has been administered on the skin.

Figure 4 shows the absolute penetrant distribution profile (in arbitrary units) in different layers of the skin as a function of applied activity (dose).

Figure 5 shows the total amount of penetrant recovered in different tissues (skin, blood, liver) at different times after the administration of an increasing quantity of ultra-deformable penetrants on the skin grows with the applied dose per area.

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Figure 7 shows the penetrant derived radioactivity in the blood as a function of epicutaneously administered dose measured 8 h or 24 h after the application.

Figure 8 shows the results obtained by measurement of the mean vapor transmission rate (MVTR) of five microporous polyethylene membranes, four polyurethane membranes and one polycarbonate track etched membrane.

Figure 9 is a diagram showing the principle of the "switching-effect," which e.g. is observed in connection with the inventive hydrophobic mesh-membranes.

Figure 10 shows the penetrability of three different microporous polyethylene membranes for Transfersomes namely Type-C; Solupor-E011 D, Solupor-8P07A and Solupor-10P05A (DSM Solutech, Heerlen, The Netherlands).

Figure 11 shows a schematic diagram of a multicompartiment patch having external compartments according to the present invention in form of twin syringe serving as storage compartments with mixing tubing or T-piece connector attached to the patch.

Figure 12 shows a schematic diagram of a multicompartiment patch according to the present invention having vertically stacked compartments.

Figure 13 shows a schematic diagram of a multicompartment patch according to the present invention with a side-by-side alignment of compartments with vertically introduced septum.

Figure 14 shows a schematic diagram of a multicompartment patch according to the present invention having a side-by-side alignment of compartments with separating lamination. - -.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance: claims 36-37, 39-41, 122-124, and 126 are allowed over the prior art of record. as indicated in the prior office action, the patch containing the specified composition and the liner with the particular vapor permeation rate is not disclosed or suggested in the prior art of record. The composition itself is disclosed in references by the same inventor as in the record. Claim 122 is equivalent to claim 40, indicated as having allowable subject matter. In claim 122 the patch is provided with a non-occlusive backing liner or porous membrane with pores between 20-100 nm, which teaching is lacking in the prior art. The patch having the claimed compositions and provided in the reservoir or liner with the particular range of pore size is not disclosed or suggested in the prior art of record. The prior art of record teaches non-occlusive liners forming part of a reservoir containing a medicament or transdermal, membranes in combination with adhesive and liners are disclosed in the art (see patent 7,063,859, 7,008,637, 6,797,276, 6,517,864), however, the range in pore size as in the present invention is not disclosed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M. Fortuna whose telephone number is (571) 272-1141. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ana M Fortuna
Primary Examiner
Art Unit 1797

Application/Control Number: 10/037,480
Art Unit: 1797

Page 6

/Ana M Fortuna/
Primary Examiner, Art Unit 1797

ATTACHMENT C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	CEVC et al.	Art Unit:	1723
Application No.	10/037,480	Examiner:	A. M. Fortuna
Date Filed:	January 4, 2002	Conf.No.	5210
Docket No.	35946-703.301 (Formerly 2001377.124US1)	Cust.No.	021971
Title:	A METHOD FOR THE IMPROVEMENT OF TRANSPORT ACROSS ADAPTABLE SEMI-PERMEABLE BARRIERS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT AND REPLY UNDER 37 C.F.R. § 1.111

This communication is in response to the Office Action mailed April 11, 2007. The shortened statutory period for response expires on July 11, 2007. This Response is submitted after the shortened statutory period for reply, therefore a three month extension fee is required to enter this Amendment. This Response is accompanied by a Petition for a three month Extension of Time under § 1.136 and required fees extending the time for response to October 11, 2007, and is therefore timely filed.

Prior to reconsidering this application on the merits, please amend the application as follows:

Amendments to the Specification begin at page **2** of this Amendment.

Amendments to the Claims are reflected in the listing of claims that begins at page **8** of this Amendment.

Replacement Drawings begin at page **10** of this Amendment.

Remarks begin at page **14** of this Amendment.

Amendments to the Specification

(1) Please add the following after Page 62, line 5, of the specification:

Brief Description of the Drawings

Figure 1 shows the recovery of relative activity (penetrant amount) in different layers of the skin as a function of applied activity (dose).

Figure 2 shows the amount of carrier derived radioactivity (^3H -DPPC) in the blood as a function of time and epicutaneously administered penetrant quantity, expressed as percentage of applied dosage.

Figure 3 indicates the relative accumulation of carrier derived radioactivity in various organs at two different time points after an increasing mass of ultradeformable carriers has been administered on the skin.

Figure 4 shows the absolute penetrant distribution profile (in arbitrary units) in different layers of the skin as a function of applied activity (dose).

Figure 5 shows the total amount of penetrant recovered in different tissues (skin, blood, liver) at different times after the administration of an increasing quantity of ultradeformable penetrants on the skin.

Figure 6 shows the time dependence of penetrant derived radioactivity in the blood as a function of epicutaneously administered suspension volume (lipid amount).

Figure 7 shows the penetrant derived radioactivity in the blood as a function of epicutaneously administered dose measured 8 h or 24 h after the application.

Figure 8 shows the results obtained by measurement of the mean vapour transmission rate (MVTR) of five microporous polyethylene membranes, four polyurethane membranes and one polycarbonate track etched membrane.

Figure 9 is a diagram showing the principle of the "switching-effect", which is observed in connection with the inventive hydrophobic mesh-membranes.

Figure 10 shows the penetrability of three different microporous polyethylene membranes to Transfersomes®.

Figure 11 shows a schematic diagram of a multicompartment patch having external compartments according to the present invention in form of a twin syringe serving as storage compartments with mixing tubing or a T-piece connector attached to the patch.

Figure 12 shows a schematic diagram of a multicompartment patch according to the present invention having vertically stacked compartments.

Figure 13 shows a schematic diagram of a multicompartment patch according to the present invention with a side-by-side alignment of compartments with vertically introduced septum.

Figure 14 shows a schematic diagram of a multicompartment patch according to the present invention having a side-by-side alignment of compartments with separating lamination.

Amendments to the Specification (cont.)

(2) Please replace the paragraph at page 31, line 28 to page 32, line 5 with the following:

Said backing liner needs ~~need~~ to be liquid-tight in order to prevent loss of active substance, which should be delivered e.g. transdermally. In order to ensure or determine if the membrane is liquid-tight, the penetrability of Transfersomes® through the membranes is measured upon application of low hydrostatic pressures. The polyethylene membranes Cotran 9711 (3M Medica, Borken Germany) and 14P10A are liquid tight up to an applied pressure of 1 MPa. Further, all cited polyurethane membranes are liquid tight.

Non-Marked-Up Version of Amendment to Specification:

Below is presented amendment (1) with the text to be added after Page 62, line 5, of the specification, without any underlining, as required by 37 C.F.R. § 1.121(b)(1)(iii):

Brief Description of the Drawings

Figure 1 shows the recovery of relative activity (penetrant amount) in different layers of the skin as a function of applied activity (dose).

Figure 2 shows the amount of carrier derived radioactivity (^3H -DPPC) in the blood as a function of time and epicutaneously administered penetrant quantity, expressed as percentage of applied dosage.

Figure 3 indicates the relative accumulation of carrier derived radioactivity in various organs at two different time points after an increasing mass of ultradeformable carriers has been administered on the skin.

Figure 4 shows the absolute penetrant distribution profile (in arbitrary units) in different layers of the skin as a function of applied activity (dose).

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Figure 6 shows the time dependence of penetrant derived radioactivity in the blood as a function of epicutaneously administered suspension volume (lipid amount).

Figure 7 shows the penetrant derived radioactivity in the blood as a function of epicutaneously administered dose measured 8 h or 24 h after the application.

Figure 8 shows the results obtained by measurement of the mean vapour transmission rate (MVTR) of five microporous polyethylene membranes, four polyurethane membranes and one polycarbonate track etched membrane.

Figure 9 is a diagram showing the principle of the "switching-effect", which is observed in connection with the inventive hydrophobic mesh-membranes.

Figure 10 shows the penetrability of three different microporous polyethylene membranes to Transfersomes®.

Figure 11 shows a schematic diagram of a multicompartment patch having external compartments according to the present invention in form of a twin syringe serving as storage compartments with mixing tubing or a T-piece connector attached to the patch.

Figure 12 shows a schematic diagram of a multicompartment patch according to the present invention having vertically stacked compartments.

Figure 13 shows a schematic diagram of a multicompartment patch according to the present invention with a side-by-side alignment of compartments with vertically introduced septum.

Figure 14 shows a schematic diagram of a multicompartment patch according to the present invention having a side-by-side alignment of compartments with separating lamination.

Non-Marked-Up Version of Amendment to Specification (cont.):

Below is presented amendment (2) with the text of the replacement paragraph for the paragraph from page 31, line 28, to page 32, line 5, without any underlining, as required by 37 C.F.R. § 1.121(b)(1)(iii):

Said backing liner needs to be liquid-tight in order to prevent loss of active substance, which should be delivered e.g. transdermally. In order to ensure or determine if the membrane is liquid-tight, the penetrability of Transfersomes® through the membranes is measured upon application of low hydrostatic pressures. The polyethylene membranes Cotran 9711 (3M Medica, Borken Germany) and 14P10A are liquid tight up to an applied pressure of 1 MPa. Further, all cited polyurethane membranes are liquid tight.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the Application:

1-35. (Canceled)

36. (Currently amended) A patch comprising: a non-occlusive backing liner and an inner liner, wherein the backing liner and the inner liner define a reservoir, the patch containing a formulation prepared by suspending or dispersing penetrants in a polar liquid in the form of fluid droplets surrounded by a membrane-like coating of one or several layers, said coating comprising at least two kinds or forms of amphiphilic substances with a tendency to aggregate, wherein said at least two substances differ by at least a factor of 10 in solubility in said polar liquid, wherein said penetrants are able to transport agents through the pores of an adaptable semi-permeable porous barrier or enable agent permeation through the pores of said barrier after penetrants have entered the pores, wherein the barrier is skin or mucosa of a mammalian body or cuticle of a plant, the pH of the formulation is between 3 and 10, and wherein the formulation is present in an amount corresponding to a desired dose per area; and
~~— a non-occlusive backing liner and (a) an inner liner, wherein the backing liner and the inner liner define a reservoir; and/or (b) a matrix layer.~~

37. (Previously presented) The patch according to claim 36, wherein the inner liner prevents unwanted release of the formulation from the patch during storage and enables rapid skin wetting when contacted with the skin.

38. (Previously presented) The patch according to claim 36 wherein the non-occlusive backing liner exhibits a mean vapor transmission rate (MVTR) of more than 1000 g/m²day.

39. (Previously presented) The patch according to claim 36 wherein the penetrant flux across the barrier is controlled by the solvent disappearance across the non-occlusive backing liner.

40. (Previously presented) The patch of claim 36 wherein the non-occlusive backing liner has pores of smaller than 100 nm.

41. (Previously presented) The patch of claim 36 wherein the non-occlusive backing liner comprises a polyurethane membrane, a polyester track-etched porous membrane, a polycarbonate track-etched porous membrane or a polyethylene microporous membrane.

42-121. (Canceled)

REPLACEMENT SHEET

11/14

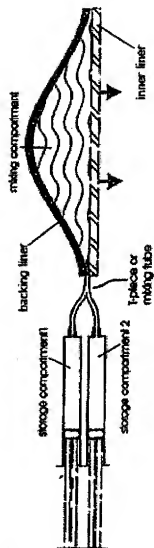


Figure 11

REPLACEMENT SHEET

12/14

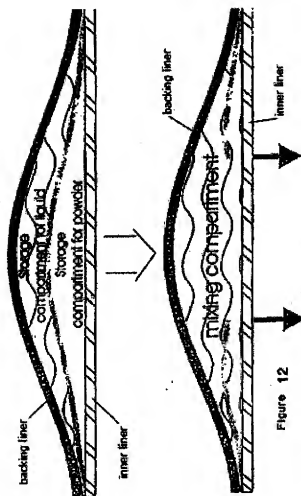


Figure 12

REPLACEMENT SHEET

13/14

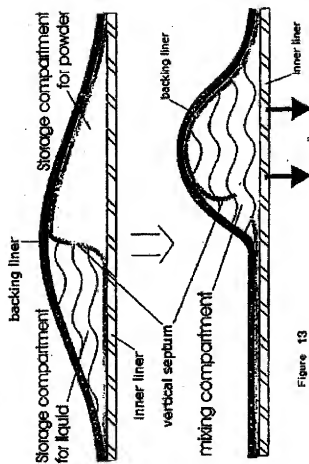
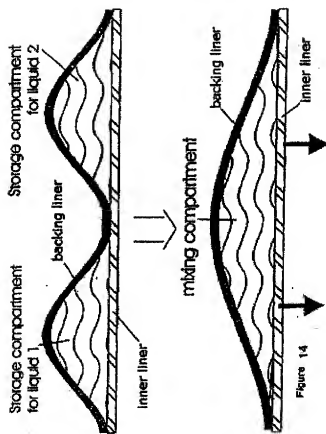


Figure 13

REPLACEMENT SHEET

14/14



REMARKS

Claims 36-41 are pending in the application. Claims 1-35 and 42-121 have been canceled without prejudice. Claim 36 has been amended. The right to prosecute the subject matter of any canceled claim in this application or in one or more continuation, continuation-in-part or divisional applications is hereby reserved. No new matter has been added.

Support in the specification for the amendment to the specification inserting a brief description of drawings can be found, for example, at page 57, line 12 to page 59, line 5; and page 59, line 19 to page 60, line 20.

Support in the specification for the replacement drawings can be found, for example, as indicated in the table, below:

11	Page 15, lines 25-6; Page 17, lines 5-7; Page 29, lines 3-4, 9-12; Page 36, lines 5-11, 23-27; Page 37, lines 2-3, 25-26; Page 38, line 21 to Page 39, line 5; Page 39, lines 14-15; Page 60, lines 6-9; Page 60, line 22 to Page 61, line 2
12	Page 17, lines 7-10; Page 29, lines 3-4; Page 37, lines 9-14, 22-23; Page 38, lines 3-8, 11-12, 14-19, line 21 to Page 39, line 5; Page 39, lines 14-15; Page 40, lines 6-7; Page 60, lines 11-12
13	Page 17, lines 7-10; Page 29, lines 3-4; Page 37, lines 9-14, 22-23; Page 38, lines 3-8, 11-12, 14-19, line 21 to Page 39, line 5; Page 39, lines 14-15; Page 40, lines 6-7; Page 60, lines 14-16
14	Page 17, lines 7-10; Page 29, lines 3-4; Page 37, lines 9-14, 22-23; Page 38, lines 3-8, 11-12, line 21 to Page 39, line 5; Page 39, lines 14-15; Page 40, lines 6-7; Page 60, lines 18-20

Support in the specification for the amended claim can be found, for example, as indicated in the table, below:

36	Page 17, line 1; Page 28, lines 2-4; Page 29, lines 4-6; Page 41, lines 23-24
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Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 36-41 have been rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

The office action alleges that it is unclear whether one of the liners constitutes the semi-permeable porous barrier. Claim 36, from which claims 37-41 depend, has been amended to recite that the adaptable semi-permeable porous barrier is skin or mucosa of a mammalian body or cuticle of a plant. The adaptable semi-permeable porous barrier is not a component of the presently claimed patch, nor is it indicated in Figures 11-14. The Examiner's attention is invited to replacement Figures 11-14, which indicate the backing and inner liners.

The office action asks whether the inner liner constitutes the semi-permeable barrier through which the penetrants permeate. The Examiner's attention is invited to amended Figures 11-14, each of which indicates an inner liner through which the penetrants can pass when the inner liner contacts the skin or mucosa of a mammalian body or cuticle of a plant. Furthermore, the skin-wetting phenomenon referred to in the office action is shown in Figure 9 and is described, for example, at page 59, lines 19-25 of the specification.

The office action also asks whether the penetrants pass through the non-occlusive porous backing liner. The Examiner's attention is invited to amended Figures 11-14, each of which indicates a backing liner. The backing liner facilitates evaporation of the polar liquid of the formulation that comprises the penetrants and is contained in the patch, as described at page 31, lines 9-10 of the specification. The evaporation of the polar liquid increases the flux of penetrants across the adaptable semi-permeable porous barrier, as described at page 31, lines 13-15 of the specification.

In view of the above and the enclosed replacement Figures 11-14, it is believed that the rejection under 35 U.S.C. § 112, second paragraph, has been overcome and should be withdrawn.

Drawings

The drawings have been objected to as being allegedly incomplete. Submitted herewith are replacement Figures 11-14, which indicate a backing liner and an inner liner in each figure. Replacement Figures 12-14 include an arrow to more clearly indicate that combining or mixing of the ingredients in each compartment can be achieved by perforating or destroying the compartment-separating membrane, as described in the specification at page 40, lines 6-7. Replacement Figure 13 also indicates a vertical septum, which is described in the specification at page 60, line 16.

The office action contends that Figures 11-14 allegedly do not identify the porous barrier by a numeral. As discussed above, claim 36, from which claims 37-41 depend, has been amended to recite that the adaptable semi-permeable porous barrier is skin or mucosa of a mammalian body or cuticle of a plant, and not a component of the presently claimed patches.

In view of the above, it is believed that the objection to the drawings has been overcome and should be withdrawn.

Disclosure

The disclosure is objected to as allegedly lacking a brief description of figures. The specification is hereby amended to include a section entitled "Brief Description of the Drawings" that includes a brief description of Figures 1-14. Thus, it is believed that the objection to the disclosure has been overcome and should be withdrawn.

Application No.: 10/037,480
Response to Office Action Mailed: April 11, 2007
Response Electronically Filed October 5, 2007

The Commissioner is authorized to debit any necessary fee or credit any overpayment relating to the above-identified application to Deposit Account No. 23-2415 (Docket No. 35946-703.301).

If the Examiner believes that any further discussion of this communication would be helpful, please contact the undersigned at the telephone number provided below.

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Professional Corporation

Dated: October 5, 2007

By: 

Maya Skubatch,
Registration No. 52,505

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